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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/761,981	01/20/2004	Mark W. Kroll	A04P1004US01	4011

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PACESETTER, INC.
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EXAMINER	
LEE, YUN HAENG NMN	

ART UNIT	PAPER NUMBER
3766	

DATE MAILED: 05/01/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/761,981	KROLL ET AL.	
	Examiner	Art Unit	
	Yun H. Lee	3766	

– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *20 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-21* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-12,14-18,20 and 21* is/are rejected.

7)☒ Claim(s) *13* is/are objected to.

8)☒ Claim(s) *19* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *20 January 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *1/20/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-18, 20 and 21, drawn to an implantable pacemaker/defibrillator device, classified in class 607, subclass 4.

   II. Claim 19, drawn to a method of installing an implantable medical device, classified in class 607, subclass 5.

The inventions are distinct, each from the other because of the following reasons:

2. Inventions II and I are related as process and apparatus for its practice. The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another and materially different apparatus or by hand, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the apparatus as claimed can be used to practice another and materially different process. The implantable pacemaker/defibrillator device can be used for cardiac pacing.

3. Because these inventions are independent or distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Derrick Reed on 4/21/06 a provisional election was made without traverse to prosecute the invention of group I, claims 1-18 and 20. Affirmation of this election must be made by applicant in replying to this Office

action. Claim 19 is withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Objections

6. Claim 14 is objected to because of the following informalities: There appears to be a typographical error in line 4. Appropriate correction is required.

7. Claim 21 is objected to because of the following informalities: There appears to be a missing noun in line 2. Examiner suggests amending the phrase "implantable medical" to "implantable medical device".

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

9. Claims 1-6, 8, 10, 11, 14-18, 20 and 21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilz et al. (US Pat. No. 6,044,295) in view of Marincic et al. (US Pat. No. 5,558,962).

Regarding claim 1, Pilz et al. discloses an implantable pacemaker/defibrillation device comprising:

pacing pulse generation circuitry (7);

defibrillation shock generation circuitry (5, col. 6 lines 1-4);

a first power source (1) to provide power for the pacing pulse generation circuitry; and

a second power source (2) employing lithium manganese dioxide ($LiMnO_2$) (col. 5 line 49) to provide power for the defibrillation shock generation circuitry.

The claim differs from the disclosed invention of Pilz et al. in that the first power source is a polycarbon monofluoride (CF_x) power source. Examiner considers the use of CF_x power sources in implantable medical devices to be conventional and well known in the art with Marincic et al. being but one example. Marincic et al. discloses a highly reliable solid CF_x cathode power source for use in a wide range of electronic devices designed for surgical implantation into humans or animals (col. 1 lines 9-56). Therefore, it would have been obvious to one of ordinary skill in that art at the time of invention to modify the first power source of Pilz et al. to be a polycarbon monofluoride (CF_x) power source in order to provide a highly reliable power source capable of providing an adequate amount of current and voltage for an extended period of time.

Regarding claim 2, Pilz et al. discloses the device of claim 1 configured as a prophylactic device for delivering defibrillation shocks in response to a single episode of ventricular fibrillation. The device of Pilz et al. is configured for delivering defibrillation shocks in response to not only a single episode of ventricular fibrillation, but also multiple episodes of ventricular fibrillation (col. 5 line 58).

Regarding claim 3, Pilz et al. discloses the device of claim 2 configured to be capable of delivering up to six defibrillation shocks in response to the single episode of ventricular fibrillation. In fact, the device of Pilz et al. can deliver more than six defibrillation shocks (col. 5 line 58).

Regarding claim 4, Pilz et al. does not expressly disclose that the individual defibrillation shocks have energies in the range of 10-40 joules. Examiner takes Official Notice of the fact that it is well known in the art of implantable defibrillators for defibrillation shocks to have energies in the range of 10 to 40 joules in order to expose the patient to the smallest amount of energy possible to minimize discomfort while maintaining a high probability of terminating an arrhythmia with the shock. Therefore, it would have been obvious to one of ordinary skill in the art at the time of invention to modify the defibrillation shock generation circuitry to provide individual shocks having energies in the range of 10 to 40 joules in order to expose the patient to the smallest amount of energy possible to minimize discomfort while maintaining a high probability of terminating an arrhythmia with each individual shock.

Regarding claim 5, Pilz et al. discloses the implantable device of claim 1 further comprising control circuitry (4) operative to control the pacing pulse generation circuitry and the defibrillation shock generation circuitry and wherein the first power source additionally provides power for the control circuitry (col. 5 lines 65-67).

Regarding claim 6, Pilz et al. discloses the implantable device of claim 1 wherein the defibrillation shock generation circuitry includes a capacitor operative to store charge for a defibrillation shock (col. 6 lines 3-4).

Regarding claim 8, Pilz et al. does not expressly disclose what type of capacitor is used. It would have been obvious to one having ordinary skill in the art at the time of invention to modify the device as taught by Pilz with an aluminum oxide shocking capacitor since it was known in the art that aluminum oxide capacitors are used to provide high energy output in shocking circuitry. In addition, Applicant discloses at page 2, paragraph 4 that the use of aluminum oxide capacitors is well known in the implantable pacemaker/defibrillator art.

Regarding claims 10, 11, 14-16, Pilz et al. does not expressly disclose what combinations of electrodes are coupled for delivering ventricular defibrillation shocks or pacing pulses. Examiner takes Official Notice of the fact that it is well known in the art to use the various electrode configurations listed here depending on the particular

application. Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to have used any of the electrode configurations specified in claims 10, 11, 14 and 15 for the delivery of ventricular defibrillation shocks and pacing pulses in the device of Pilz et al.

Regarding claims 17, 18 and 20, the limitations have been met by the above discussion of claim 1.

Regarding claim 21, Pilz et al. discloses a method for providing pacing and defibrillation therapy using an implantable medical device having pulse generation circuitry and defibrillation shock generation circuitry, comprising the steps of:

upon detecting a need for pacing therapy, selectively delivering power from a first power source (1) to pacing pulse generation circuitry for generating pacing pulses (col. 3 lines 39-40); and

upon detecting a need for ventricular defibrillation therapy, selectively delivering power from a second power (2) source employing lithium manganese dioxide ($LiMnO_2$) to the defibrillation shock generation circuitry for generating shocks for ventricular defibrillation (col. 3 lines 38-39).

Regarding the employment of polycarbon monofluoride (CF_x) in the first power source, see above discussion of claim 1.

10. Claims 7 and 9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Pilz et al. (US Pat. No. 6,044,295) in view of Marincic et al. (US Pat. No. 5,558,962) as applied to claim 1 above, and further in view of Norton et al. (US Pat. Appl. Pub. No. 20040243183). Pilz et al. does not expressly disclose what type of capacitor is used. Pilz et al. is also silent regarding reformation of the capacitors. Norton teaches of using a tantalum capacitor (paragraph 29 lines 1-2) which does not require reformation in implantable defibrillators for the advantage of having an extended battery life due to elimination of non-therapeutic charging required by reformation (paragraph 13) and greatly improved efficiency of capacitor charging (paragraph 15). Thus, it would have been obvious to one of ordinary skill in the art at the time of invention to include non-reformation based defibrillation generation circuitry with a tantalum capacitor in order to extend battery life and greatly improve efficiency of capacitor charging.

11. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Pilz et al. (US Pat. No. 6,044,295) in view of Marincic et al. (US Pat. No. 5,558,962) as applied to claim 1 above, and further in view of Regna (US Pat. No. 4,796,630). Pilz et al. does not expressly disclose that shunt diodes interconnect the right ventricular tip and ring electrodes and right atrial tip and ring electrodes, respectively. Regna discloses a cardiac pacemaker that has combined defibrillation and electrosurgery protection (see Regna Abstract). Regna further discloses a protection circuit interposed between a tip 36 and ring 38 electrode including a zener diode, read as a shunt diode 42 (see Regna Fig. 2 and col. 3, lines 1-11). Regna further discloses that such a protection circuit may

be utilized with a dual chamber pacemaker and that the shunt diode 42 protects the pacing circuitry from any defibrillation shock energies that may be applied across the heart of the patient (see Regna col. 1, lines 35-52 and col. 3, lines 50-60). It would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Pilz et al. to include shunt diodes interconnected between the right ventricular tip and ring electrodes and right atrial tip and ring electrodes, respectively in order to provide defibrillation and electrosurgery protection to the pacing pulse generation circuitry.

Double Patenting

12. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

13. Claims 1 and 2 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1 and 8 of copending Application No. 10/761,907. Although the conflicting claims are not identical, they are not patentably distinct from each other because claim 8 of the copending application (which includes all the limitations of its parent claim, claim 1) recites all the limitations of claims 1 and 2 of the current application.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Allowable Subject Matter

14. Claim 13 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

15. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yun H. Lee whose telephone number is (571) 272-2847. The examiner can normally be reached on M-Th 9-7.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 3766

yhl